In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS No. 21-0055V UNPUBLISHED

ELLEN RODRIGUEZ,

Petitioner,

٧.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: August 23, 2022

Special Processing Unit (SPU); Findings of Fact; Site of Vaccination; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Bridget Candace McCullough, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT¹

On January 5, 2021, Ellen Rodriguez filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*² (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA"), as defined in the Vaccine Table, after receiving the influenza ("flu") vaccine on November 14, 2018. Petition at 1, ¶¶ 2, 19.

For the reasons discussed below, I find the flu vaccine was most likely administered in Petitioner's left deltoid, as alleged.

¹ Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

I. Relevant Procedural History

After the claim's initiation, Ms. Rodriguez filed the affidavit and medical records required under the Vaccine Act. Exhibits 1-11, ECF Nos. 1, 5 (Notice of Filing for CD received on Jan. 25, 2021), 9; see Section 11(c). On April 14, 2021, the case was activated and assigned to the Special Processing Unit (OSM's process for attempting to resolve certain, likely-to-settle claims (the "SPU")). ECF No. 11.

On May 12, 2022, Respondent indicated that he wished to file a Rule 4(c) Report and to engage in informal discussions regarding the appropriate amount of compensation in this case. ECF No. 23. Because the vaccine record indicates Petitioner received the flu vaccine in her right (opposing) deltoid, rather than her left deltoid as alleged, the parties requested a factual finding regarding the site of vaccination. Joint Motion for Fact Ruling ("Motion"), filed July 11, 2022, ECF No. 26. In response to an email inquiry, Respondent confirmed that he still planned to file a Rule 4(c) Report in this case, after I address the situs issue. See Informal Remark, dated July 29, 2022.

The matter is now ripe for adjudication.

II. Issue

At issue is whether Petitioner received the vaccination alleged as causal in her injured *left* shoulder, rather than her *right* shoulder as the vaccine record indicates.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); see also Burns v.

Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make the finding regarding site of vaccination after a complete review of the record to include all medical records, affidavits, and additional evidence filed. Specifically, I note the following evidence:

- Prior to vaccination in 2017 and 2018, Petitioner suffered significant radiculopathy, lower back pain, difficulty walking, severe neck pain and loss of head control. Exhibits 6, 8. After reporting improvement in early January 2018, she was discharged from physical therapy ("PT"). Exhibit 8 at 3-4.
- Petitioner received the flu vaccine alleged as causal during a visit to her allergist on November 14, 2018. Exhibit 4 at 30-31. The vaccine record a list of three vaccines received in 2015-18 indicates the flu vaccine was administered in her right deltoid, rather than left deltoid. At the bottom of this form, it is noted that the record was "generated by eClinicalWorks EMR/PM Software." Id.
- Two days post-vaccination, it appears Petitioner called an individual at her allergist's clinic complaining of pain and an inability to lift her arm after receiving her flu shot. Exhibit 4 at 33. Although this record was created on November 27th, the record itself indicates the call was placed on November 16th when the author was not at work. The record does not identify the arm being discussed. *Id.*
- On November 26, 2018, Petitioner visited an orthopedist for left shoulder pain which began two weeks earlier after a flu shot. Exhibit 10 at 20. The orthopedist administered a cortisone injection and recommended she attend PT. Id.
- That same day (November 26th), Petitioner attended PT for left shoulder pain, weakness, and heaviness. Exhibit 15 at 11. There is no mention of the flu vaccine <u>or</u> any other cause for her pain. *Id.* at 11-14. Petitioner estimated the level of her pain as seven out of ten: five at best and ten at worst. *Id.* at 11.

- After her visit to the orthopedist and PT, Petitioner called her allergist, providing an update on her shoulder injury following receipt of the flu vaccine and indicating she would call the CDC to see if it had been reported. Exhibit 4 at 32 (November 26th call).
- By her fourth PT session on December 4th, Petitioner reported "significant improvement" in her left shoulder pain. Exhibit 15 at 5.
- On June 27, 2019, Petitioner returned to the orthopedist, complaining of left shoulder pain which started approximately six months earlier after a flu shot. Exhibit 10 at 19. It was noted that she had obtained significant improvement after a corticosteroid inject and PT, but that her pain had returned in May 2019. The orthopedist recommended Petitioner undergo an MRI. *Id.*
- Performed on July 11th, the MRI revealed "[a]cromioclavicular osteoarthritis with trace subacromial-subdeltoid bursitis." Exhibit 10 at 57.
- Petitioner returned to the orthopedist on July 17th, to discuss the results of her MRI. Exhibit 10 at 18. At this visit, the onset of her left shoulder pain was again linked to "a flu shot in the left shoulder." *Id.* The orthopedist administered a second cortisone injection. *Id.*
- Petitioner continued to attend PT and seek orthopedic treatment of her left shoulder pain through the remainder of 2019 and early 2020. Exhibit 7; Exhibit 10 at 12-17.
- In her affidavit, executed on January 25, 2021, Petitioner indicated that she received the flu vaccine in her left deltoid on November 14, 2018, at her allergist's clinic. Exhibit 11 at ¶ 3.

The above medical entries establish that when seeking medical treatment on multiple occasions during the year and a half following the November 2018 vaccination, Petitioner consistently reported left shoulder pain attributed to that vaccination. She also sought treatment close in time to her injury – reporting her vaccine-related injury to the administering clinic two days post-vaccination and visiting an orthopedist less than two weeks later. Petitioner consistently reported that her left shoulder pain began after her flu shot administered in the same arm.

Based upon my experience resolving SPU SIRVA cases (more than 1,200 cases since my appointment as Chief Special Master) as well as additional SIRVA cases handled on my regular docket, I find it is not unusual for the information regarding site of vaccination to be incorrect.³ In many instances, the information regarding situs is recorded prior to vaccination, and is not updated - even if the vaccine is then administered in the opposing arm. Thus, although such records are unquestionably the first-generated documents bearing on issues pertaining to situs, they are not per se reliable simply because they come first – and in fact the nature of their creation provides some basis for not accepting them at face value.

Here, the vaccine record – a list of three vaccines received in 2015-18 which appears to have been printed from computerized records using a software program - is the *only* evidence in this case which supports a finding of right arm situs. And it is not clear when and by whom this record was created. Accordingly, given the general unreliability of these administration documents in the experience of SPU SIRVA cases, this evidence alone is not sufficient to counter Petitioner's clear, consistent, and close-intime reports of left shoulder pain after receiving the flu vaccine *in her left arm* on November 14, 2018.

V. Scheduling Order

Petitioner has indicated that she expects to have collected all documentation needed to support her demand by next week - August 26, 2022. ECF No. 27. And Respondent estimates he can file his Rule 4(c) Report two week after my ruling. Motion at 3.

Petitioner shall file a status report updating me on her efforts to finalize her demand and to obtain any needed supporting documentation by no later than <u>Wednesday</u>, <u>September 07</u>, <u>2022</u>. The status report should indicate the date by which Petitioner conveyed or expects to convey her demand and supporting documentation to Respondent.

Respondent shall file his Rule 4(c) Report by no later than <u>Wednesday</u>, <u>September 07, 2022</u>.

³ See, e.g., Arnold v. Sec'y of Health & Hum. Servs., No. 20-1038V 2021 WL 2908519, at *4 (Fed. CL. Spec. Mstr. June 9, 2021); Syed v. Sec'y of Health & Hum. Servs., No. 19-1364V, 2021 WL 2229829, at *4-5 (Fed. Cl. Spec. Mstr. Apr. 28, 2021); Ruddy v. Sec'y of Health & Hum. Servs., No 19-1998V, 2021 WL 1291777, at *5 (Fed. Cl. Spec. Mstr. Mar. 5, 2021); Desai v. Sec'y of Health & Hum. Servs., No 14-0811V, 2020 WL 4919777, at *14 (Fed. Cl. Spec. Mstr. July 30, 2020); Rodgers v. Sec'y of Health & Hum. Servs., No. 18-0559V, 2020 WL 1870268, at *5 (Fed. Cl. Spec. Mstr. Mar. 11, 2020); Stoliker v. Sec'y of Health & Hum. Servs., No. 17-0990V, 2018 WL 6718629, at *4 (Fed. Cl. Spec. Mstr. Nov. 9, 2018).

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran Chief Special Master